JUL 1 7 2001

K011264
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510(k) SUMMARY

510(k) NUMBER: PENDING

SUBMITTED BY: Applied Medical Resources Corporation
22872 Avenida Empresa
Rancho Santa Margarita, CA-92688
(949) 713-8327

CONTACT PERSON: Anil Bhalani
Director of Regulatory Affairs and Clinical Programs

DATE OF PREPARATION: April 24, 2001

NAME OF DEVICE: Mesh Ureteral Stent

CLASSIFICATION NAME: Ureteral Stent, 21 CFR 876.4620.

TRADE NAME: Not Determined

PREDICATE DEVICES:
1. Applied Medical's Ureteral Stents (K991219), Applied Medical Resources, Rancho Santa Margarita, CA.
2. Bard Lubricious Ureteral Stent (K983489), C. R. Bard, Inc.

SUMMARY STATEMENT:

The Applied Medical Ureteral Stent is indicated for use as a temporary indwelling ureteral catheter, to assist in urine drainage in patients who require a ureteral stent after a diagnostic ureteroscopic procedure, ureteroscopic stone fragmentation, or prior to shockwave lithotripsy. The stent may be placed using retrograde endoscopic and or fluoroscopic techniques.

The Mesh Ureteral Stent has a kidney coil similar in design and materials to conventional stents and a lower body and bladder coil similar in design to conventional stents made from a polyester mesh. The two materials are heat fused together. The lower section of the mesh design is expected to improve comfort due to its softer and more flexible construction, which is expected to take the shape of the ureter, exerting less force against the ureter wall resulting in less discomfort when compared to a more rigid conventional stent.

The Mesh Ureteral Stent has a crossing profile of 7 French and will be available in lengths ranging from 20 to 30 centimeters. The stent has a double pigtail design with a full retentive coil at each end. A nylon tether is attached to the bladder coil to aid in placement and removal of the stent. The stent is designed for placement over a guidewire of up to .038 inches in diameter that is pre-positioned through the urological tract. The stent is supplied along with a positioner tube.

Tests appropriate for the Mesh Ureteral Stent were selected and configured to meet requirements of its unique design. The FDA Guidance "*Guidance for the Content of Premarket Notifications for Ureteral Stents*" and ASTM Standard, F 1828-97, Standard Specification for Ureteral Stents were used to design the performance tests. Based on the testing performed and data collected, a conclusion was made that the Mesh Ureteral Stent performs as intended.

The Applied Medical Ureteral Stents are substantially equivalent to predicate devices and introduce no new safety and effectiveness issues when used as instructed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 2001

Mr. Anil Bhalani
Director of Regulatory Affairs
and Clinical Programs.
22872 Avenida Empresa
Rancho Santa Margarita, CA 92688

Re: K011264
Mesh Ureteral Stent
Dated: April 24, 2001
Received: April 25, 2001
Regulatory Class: II
21 CFR §876.4620/Procode: 78 FAD

Dear Mr. Bhalani:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

K011264

INDICATIONS FOR USE

Applied Medical Resources is providing this separate cover page for the Ureteral Stents "Indications for Use" as required.

510(k) Number: Not assigned

Device Name: Ureteral Stent

Indications for Use: The Applied Medical Ureteral Stent is indicated for use as a temporary indwelling ureteral catheter, to assist in urine drainage in patients who require a ureteral stent after a diagnostic ureteroscopic procedure, ureteroscopic stone fragmentation, or prior to shockwave lithotripsy. The stent may be placed using retrograde endoscopic and or fluoroscopic techniques.

Signature: _____ Title: *Director RA/Clinical Programs* Date: *4-24-01*

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The -Counter Use _____
(Per 21 CFR 801.109)

(Optional Format -2-96)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K011264